



DJO, LLC

TO CMS VIA EMAIL/Web Posting

A DJO Global Company

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Dear Ms. Meisenberg, Ms. Burton, and Dr. Miller:

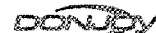
DJO Global, Inc. (DJO) appreciates the opportunity to submit comments on CMS's review of national Medicare coverage of the use of transcutaneous electrical nerve stimulation (TENS) for chronic low back pain.

DJO is a leading global developer, manufacturer, and distributor of high-quality medical devices and services that provide solutions for pain management, musculoskeletal health, and vascular health. Our products address the continuum of patient care, from injury prevention to rehabilitation after surgery, injury, or from degenerative disease, enabling people to regain or maintain their natural motion. Our Empi product line includes electrical stimulation and other orthopedic products used for pain management, orthopedic rehabilitation, and physical therapy.

DJO supports continued Medicare coverage of TENS for chronic low back pain to preserve Medicare beneficiary access to this important and effective technology. As discussed in additional detail below:

- CMS should not base a more restrictive Medicare TENS coverage policy on a single article, which we believe reaches an erroneous conclusion based on questionable and limited selection of literature. Specifically, the recommendation by Richard M. Dubinsky and Janis Miyasaki is based on only two studies, one of which focuses on patients with multiple sclerosis (MS) who have different medical profiles than the typical Medicare patient with chronic back pain, and the other of which appears not to have adequately accounted for intensity of stimulation, or timing of pain measurement.
- Dubinsky and Miyasaki acknowledge that other studies demonstrated a benefit for TENS for chronic back pain. In fact, the two positive Class II trials cited by the authors on their own would be sufficient to conclude that TENS is an effective treatment for chronic lower back pain under the author's standard. Even the *Neurology* editorial accompanying the Dubinsky and Miyasaki article concludes that "Taking the favorable benefit-risk ratio when compared with other pain relieving methods into account, TENS remains a valuable part in the armamentarium of pain therapy."
- Numerous clinical studies show positive benefits associated with the use of TENS for chronic musculoskeletal pain, including chronic low back pain.
- Each Medicare Durable Medical Equipment Medicare Administrative Contractor (DME MACs) has established a local coverage determination for TENS for chronic pain. The LCDs establish rigorous criteria, including physician-signed Certificates of Medical

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Necessity, to ensure that use of TENS is reasonable and necessary on an initial and ongoing basis.

- Clinical evidence clearly shows that TENS used for chronic low back pain meets the statutory "reasonable and necessary" criteria under § 1862(a)(1)(A), since TENS, when properly administered, is an effective treatment for low back pain.
- CMS raises the possibility of coverage for TENS for chronic low back pain under 1862(a)(1)(E), which pertains to items and services used in certain research. There is no reasonable justification for denying Medicare beneficiaries the documented, safe pain relief available through TENS use while additional research is conducted. Restricting access to this technology could lead to greater use of potentially addictive opioids and even surgical intervention.
- DJO strongly urges CMS not to restrict Medicare coverage for TENS for chronic low back pain but rather adopt the coverage criteria established by the DME MACs.

Our detailed comments follow.

Overview of TENS Technology

Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive therapy indicated for the symptomatic relief from, and management of, chronic intractable pain and post-surgical and post-trauma acute pain. For over 30 years, the medical community has used TENS as a safe and effective alternative to pharmacological approaches to pain control for many patients. TENS has minimal side effects and is non-addictive.

Pain messages transmitted by the peripheral nervous system to the brain are electro-chemical in nature. Controlling or overriding these nociceptive impulses can bring about significant pain relief to patients. With a TENS system, a portable stimulator generates a current which flows through leads to electrodes placed in specific locations on the patient's skin. The low voltage current causes an electrical reaction in sensory and motor nerve fibers, overriding pain message transmission. TENS also can stimulate endorphin production. While TENS technology varies, Empi's products offer a combination of sensory/muscle fasciculation level stimulation to provide immediate relief in addition to longer carryover of endorphin based mechanism of relief.

Due to the unique and individual nature of pain, patients respond differently to various sequences of TENS stimulation; therefore the frequency and intensity of the stimulus are carefully controlled. Likewise, changes in the patient's symptoms and response may require reevaluation and systematic modification of electrode placements and stimulating parameters for optimal response.

CMS Coverage Review Is Based on Single Article With Erroneous Recommendation

CMS cites the following rationale for opening a national coverage review for TENS used for chronic low back pain:

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In 2010, the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology published a report finding transcutaneous electrical nerve stimulation (TENS) ineffective for chronic low back pain.

DJO has strong objections to CMS basing a more restrictive Medicare TENS coverage policy on this single review, which we believe reaches an erroneous conclusion based on a limited selection of literature. The Therapeutics and Technology Assessment Subcommittee report referenced by CMS was published in a *Neurology* article authored by Richard M. Dubinsky and Janis Miyasaki (Dubinsky and Miyasaki¹). Dubinsky and Miyasaki base their conclusions on only two studies of TENS therapy (Warke et al² and Deyo et al.³), one of which focuses on patients with very different medical profiles than the typical Medicare patient with chronic back pain, and the other of which may not have adequately accounted for intensity of stimulation. The authors' criteria for excluding reports appear to be somewhat arbitrary. Nevertheless, the authors acknowledge that two other placebo-controlled randomized controlled trials reviewed – but not reflected in the author's recommendations – demonstrated a benefit for TENS for chronic back pain. Other studies that were not included in the Dubinsky and Miyasaki review provide additional evidence in support of the use of TENS for chronic low back pain (see section III below).

The first study cited by Dubinsky and Miyasaki, the Warke study, was limited to reviewing the efficacy of TENS for chronic low back pain among patients with MS. Given that MS is a complex disease of the central nervous system, TENS treatment outcomes involving this patient population cannot be generalized to the broader Medicare population with commonly-observed chronic low back pain. Medicare coverage policy for the general population therefore should not be modified in response to this study of only patients with MS.

The Deyo study involved patients who first received conventional high-frequency TENS for two weeks, then were instructed in lower-dose TENS, and then "the subjects selected the mode they preferred for the last two weeks of treatment." The physical assessments and questionnaires were completed as long as two months after the end of the treatment. This is a critical design flaw, since studies show that the effect of TENS is greatest during the actual TENS treatment and in the period of up to 12 to 24 hours after the end of treatment (Leonard et. al⁴, Marchand et. al⁵, Melzack et al⁶). In addition, the patient-selected mode apparently could have been so low that "stimulation was sometimes below a person's threshold of perception" in order to account for the sham TENS units serving as the study control. The authors did not report what type or intensity

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- 1 Dubinsky RM, Miyasaki J. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review): report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2010;74:173-176.
 - 2 Warke K, Al-Smadi J, Baxter D, Walsh D, Lowe-Strong A. Efficacy of transcutaneous electrical nerve stimulation (tens) for chronic low-back pain in a multiple sclerosis population: a randomized, placebo-controlled clinical trial. *Clin J Pain* 2006;22:812– 819.
 - 3 Deyo R, Walsh N, Martin D, Schoenfeld L, Ramamurthy S. A controlled trial of transcutaneous electrical nerve stimulation (TENS) and exercise for chronic low back pain. *N Engl J Med* 1990;1627–1634.
 - ✓ 4 ✓ Leonard G, Courtier C, Marchand S. Reduced analgesic effect of acupuncture-like TENS but not conventional TENS in opioid-treated patients. *J Pain* 2010. 2011
 - ✓ 5 Marchand S, Charest J, Li J, Chemard JR, Lavignolle B, Laurencelle L. Is TENS purely a placebo effect? A controlled study on chronic low back pain. *Pain* 1993;54:99-106.
 - ✓ 6 Melzack R, Vetere P, Finch L. Transcutaneous electrical nerve stimulation for low back pain. *Phys Ther* 1983;63:489-493.

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of simulation ultimately was used under the "patient choice" option, even though results after treatment at the patient's preferred mode was the author's primary outcome. Researchers who approach pain management from a pharmacological perspective may not have the same familiarity with the TENS technology as specialists in this area, and may not be sensitive to the importance of adequate intensity and optimal placement of electrodes in assessing the efficacy of TENS intervention/treatment. Research indicates, however, that adequate stimulation intensity is critically linked to TENS effectiveness (Rakel 2003⁷; Bjordal 2003⁸; Rakel 2009⁹, Moran et al.¹⁰). Thus, the timing of assessment of the results together with the lack of any information regarding the intensity of treatment selected by trial subjects prevents meaningful analysis of the data and significantly undermines the author's conclusions.

We therefore believe that both studies characterized as "Class I" by Dubinsky and Miyasaki have significant shortcomings. Further, if even just one of these studies is disregarded for being based on non-representative patient population or being designed with undefined stimulation parameters, there would not be sufficient evidence under the "Rating Scheme for the Strength of the Recommendations" used by the authors to support a recommendation that the treatment is "established as ineffective" – the whole basis of the CMS review.

Given the shortcomings of the two "Class I" trials as a basis for Medicare coverage, greater weight should be given to the two studies characterized as "Class II" that Dubinsky and Miyasaki acknowledged did show moderate pain reduction benefits but which were not reflected in the author's recommendations (Tulgar et al and Marchand et al). In fact, the Marchand study, a double-blinded placebo controlled trial of TENS for chronic low back pain, showed a 43% reduction in pain with active TENS that was significantly greater than the 17% reduction in pain provided by placebo TENS, and no significant changes in a control group that did not receive treatment. Tulgar and colleagues performed a comparative effectiveness review involving three forms of TENS. Among other things, the authors determined that benefit was reported in 8 of 11 patients who had frequency-modulated stimulation.

There are many other favorable studies that we believe should have been considered in the Dubinsky and Miyasaki review, and should be considered in any CMS coverage review. Nevertheless, the two positive "Class II trials" cited by the authors on their own would be sufficient to form the basis of a determination supporting the effectiveness of TENS as a treatment for chronic lower back pain under the "Rating Scheme for the Strength of the Recommendations" used by the authors. We also would point out that the *Neurology* editorial accompanying the Dubinsky and Miyasaki article concludes that "Taking the favorable benefit-risk ratio when compared with other pain relieving methods into account, TENS remains a valuable part in the armamentarium of pain therapy."¹¹

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- 7 Rakel B, Frantz R. Effectiveness of transcutaneous electrical nerve stimulation on postoperative pain with movement. *Journal of Pain* 2003;4:455-464.
 - 8 Bjordal JM, Johnson MI, Ljunggreen AE. Transcutaneous electrical nerve stimulation (TENS) can reduce postoperative analgesic consumption. A meta-analysis with assessment of optimal treatment parameters for postoperative pain. *Eur J Pain* 2003;7:181-188.
 - 9 ✓ Rakel B, Cooper N, Adams HJ, Messer BR, Frey Law LA, Dannen DR, Miller CA, Polehna AC, Ruggle RC, Vance CG, Walsh DM, Sluka KA. A New Transient Sham TENS Device Allows for Investigator Blinding While Delivering a True Placebo Treatment. *J Pain* 2009.
 - ✓ (10) Moran F, Leonard T, Hawthorne S, Hughes CM, Crum-Gardner E, Johnson MI, Rakel BA, Sluka KA, Walsh DM. Hypoalgesia in Response to Transcutaneous Electrical Nerve Stimulation (TENS) Depends on Stimulation Intensity. *J Pain* 2011;12:929-935.
 - 11 Binder A, Baron R. Utility of transcutaneous electrical nerve stimulation in neurologic pain disorders. *Neurology*. 2010 Jan 12;74(2):104-5.



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In sum, DJO does not believe that the Dubinsky and Miyasaki article provides a reasonable foundation for considering a more restrictive Medicare coverage policy for TENS for chronic low back pain.

There is Strong Clinical Support for TENS Not Reflected in Dubinsky Article

The Dubinsky and Miyasaki article discussed a very small portion of the clinical literature on TENS. In addition to the positive Tulgar and Marchand studies acknowledged by Dubinsky and Miyasaki, numerous other studies show positive benefits associated with the use of TENS for chronic musculoskeletal pain, including chronic low back pain.

For instance, Johnson and Martinson¹² conducted a meta-analysis of data from 29 papers with 38 studies on the efficacy of transcutaneous and percutaneous electrical nerve stimulation (collectively, ENS) for patients with chronic musculoskeletal pain.¹³ For all studies combined, pain was reduced significantly using ENS compared to the placebo. Further, the authors analyzed the TENS studies *alone* and found the results statistically significant for pain reduction.

Leonard and colleagues¹⁴ examined the efficacy of low and high frequency TENS in patients who were opioid tolerant and those who were not opioid tolerant. They showed a significant reduction in pain during and immediately after conventional TENS (high frequency) when compared to baseline for both the opioid and nonopioid group. For acupuncture-like TENS (low frequency), the analgesic effect of TENS was observed in the nonopioid group. The majority of the patient population in the trial had spine pain.

In a study of adults over 60 years of age, Grant and colleagues found approximately a 50% reduction in pain and reduced pain medication intake in subjects with chronic low back pain treated with TENS compared to acupuncture.¹⁵ In two randomized, double-blind, placebo controlled clinical trials focusing on older individuals (over 50 years old), Zambito and colleagues found a significant reduction in pain and disability after treatment with interferential current (a form of TENS) in older adults with vertebral column fractures and in those with degenerative disk disease without radiculopathy.^{16,17}

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- 12 Johnson M, Martinson M. Efficacy of electrical nerve stimulation for chronic musculoskeletal pain: a meta-analysis of randomized controlled trials. *Pain* 2007
 - 13 The Johnson and Martinson analysis includes musculoskeletal pain in various anatomical locations (including back, neck, hip, and knee), since "mechanism, rather than anatomical location of pain, is likely to be a critical factor for therapy." The authors note that "both proposed modes of action for ENS (the gate control theory or the release of endogenous endorphins) are not dependent upon anatomical locus." Likewise, a practitioner treats "diagnosis of musculoskeletal pain using a general multimodal approach that is not joint or location specific."
 - 14 Leonard G, Courtier C, Marchand S. Reduced analgesic effect of acupuncture-like TENS but not conventional TENS in opioid-treated patients. *J Pain* 2010.
 - 15 ✓ Grant DJ, Bishop-Miller J, Winchester DM, Anderson M, Faulkner S. A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly. *Pain* 1999;82:9-13.
 - 16 ✓ Zambito A, Bianchini D, Gatti D, Rossini M, Adami S, Viapiana O. Interferential and horizontal therapies in chronic low back pain due to multiple vertebral fractures: a randomized, double blind, clinical study. *Osteoporos Int* 2007;18:1541-1545.

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Meizack and colleagues studied the effect of TENS compared to massage in people with chronic low back pain, and found that pain reduction was significantly greater with TENS than massage, with participants reporting a pain reduction of 70-80% on the McGill pain questionnaire.¹⁸

Another meta-analysis of TENS effectiveness for individuals with non-specific low back pain performed by Machado and colleagues supported a favorable effect of active TENS over placebo.¹⁹

Taken together, these studies illustrate that numerous clinical trials demonstrate the value of TENS in relieving chronic lower back pain.

Local Medicare Coverage Policies Carefully Address Standards for TENS Use

Each of the Medicare DME MACs has established a local coverage determination for TENS, covering both use for acute post-operative pain and chronic pain. The policies establish rigorous criteria for determining whether the use of TENS is reasonable and necessary for Medicare beneficiaries on both an initial and ongoing basis. Specifically, with regard to chronic pain:

- The medical record must document the location of the pain, the duration of time the patient has had the pain, and the presumed etiology of the pain.
- The pain must have been present for at least three months.
- Other appropriate treatment modalities must have been tried and failed, and the medical record must document what treatment modalities have been used.
- The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy (certain conditions are excluded from coverage, including tempomandibular joint pain, visceral abdominal pain, headaches, and pelvic pain).
- When used for the treatment of chronic, intractable pain, the TENS unit must be used by the patient on a trial basis for a minimum of one month (30 days), but not to exceed two months.
- The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain.

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- 17 ✓ Zambito A, Bianchini D, Gatti D, Viapiana O, Rossini M, Adami S. Interferential and horizontal therapies in chronic low back pain: a randomized, double blind, clinical study. CLIN EXP RHEUMATOL 2006;24:534-539.
- 18 ✓ Melzack R, Vetere P, Finch L. Transcutaneous electrical nerve stimulation for low back pain. Phys Ther 1983;63:489-493.
- 19 ✓ Machado LA, Kamper SJ, Herbert RD, Maher CG, McAuley JH. Analgesic effects of treatments for non-specific low back pain: a meta-analysis of placebo-controlled randomized trials. Rheumatology (Oxford) 2009;48:520-527.

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- For coverage of a purchase, the physician must determine that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.
- The physician's records must document a reevaluation of the patient at the end of the trial period, must indicate how often the patient used the TENS unit, the typical duration of use each time, and the results.
- The physician ordering the TENS unit must be the attending physician or a consulting physician for the disease or condition resulting in the need for the TENS unit.

These policies already establish sufficient safeguards to ensure that TENS are used for medically-necessary purposes under the Medicare program.

TENS Meets Standards for Continued Coverage under § 1862(a)(1)(A)

CMS states that it is considering coverage for TENS under Section 1862(a)(1)(A) and Section 1862(a)(1)(E) of the Social Security Act. Section 1862(a)(1)(A) provides that:

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

Clinical evidence clearly shows that TENS used for chronic low back pain meets the statutory criteria under § 1862(a)(1)(A), as there is ample evidence that TENS, when properly administered, is reasonable and necessary as an effective treatment for low back pain.

CMS raises the possibility of coverage for TENS for chronic low back pain under 1862(a)(1)(E), which addresses payment for items and services used in certain research. CMS further requests comments that "pertain to clinical studies falling under the Coverage with Evidence Development (CED) paradigm." CED is a rarely-used pathway to allow Medicare coverage when items or services should be restricted to specific patients or specific providers with special training, if the item may be misused, or if it significantly changes how providers manage patient care, or if additional approved clinical research studies are necessary to gather more evidence.

Like any medical technology, additional research could be useful in informing and refining optimal pain treatment practices. However, there is no reasonable justification for denying Medicare beneficiaries with chronic low back pain the documented, safe pain relief available through the proper use of TENS while such studies are ongoing. Restricting access to this technology instead could necessitate greater use of potentially addictive narcotics and in some cases result in the need for surgical intervention.

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Conclusion: Continue Current Medicare TENS Coverage

Clinical evidence demonstrates that TENS used for chronic low back pain meets the statutory "reasonable and necessary" criteria under § 1862(a)(1)(A). DJO therefore strongly urges CMS not to restrict Medicare coverage for TENS for chronic low back pain beyond the criteria established by the DME MACs.

We would be pleased to answer any questions you may have or to provide additional information.

Sincerely,

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